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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/884,889

06/19/2001

Dan E. Robertson

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04/10/2003

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EXAMINER

PROUTY, REBECCA E

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/10/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,889

Applicant(s)

Robertson et al.

Examiner

Rebecca Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 2, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above, claim(s) 1-41 and 56-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13 6) ☐ Other: _____

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Applicant's election without traverse of Group IV, Claims 42-55 in Paper No. 14 is acknowledged.

Claims 1-41 and 56-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 14.

In view of the papers filed 6-6-02, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Jay M. Short and Eric J. Mathur as co-inventors.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Claims 42-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claim 42 (claims 43-55 dependent thereon) is indefinite in the recitation of "obtaining a nucleic acid comprising a sequence

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selected from the group consisting of SEQ ID NOS: 5, 7, sequences substantially identical thereto, sequences complementary thereto, fragments comprising at least 30 consecutive nucleotides thereof, and fragments comprising at least 30 consecutive nucleotides of the sequences complementary to SEQ ID NOS: 5, 7" for the following reasons.

The claim is indefinite in the recitation of "sequences complementary thereto" as it is unclear if the term "thereto" refers to SEQ ID NOS: 5 or 7 or "the substantially identical" sequence. The claim is also indefinite in the recitation of "fragments comprising... thereof" as it is unclear which nucleic acids are being referred to by the term "thereof". Since the term "substantially identical" in regard to nucleic acid sequences has been defined in the specification (page 9), the claim will be interpreted as being drawn to a method of generating a variant comprising obtaining a nucleic acid selected from the group consisting of (a) the polynucleotide of SEQ ID NO: 5, (b) any polynucleotide having at least 50% sequence identity to any fragment of the polynucleotide of SEQ ID NO: 5, (c) any polynucleotide which is completely complementary to (a) or (b), (d) a fragment of at least 30 consecutive nucleotides of (a), (b), or (c), (e) the polynucleotide of SEQ ID NO: 7, (f) any polynucleotide having at least 50% sequence identity to any

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fragment of the polynucleotide of SEQ ID NO: 7, (g) any polynucleotide which is completely complementary to (e) or (f), (h) a fragment of at least 30 consecutive nucleotides of (e), (f), or (g). Correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42, 43, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Trakulnaleamsai et al. as evidenced by Loprasert et al. (reference AC of applicant's PTO-1449)

Trakulnaleamsai et al. teach random mutagenesis of the *Bacillus stearothermophilus* catalase gene comprising isolating a 2.7 kb restriction fragment of the gene, chemically mutagenizing this fragment, reinserting it into an expression vector, and producing the mutant catalase. As Loprasert et al. evidence that the *Bacillus stearothermophilus* catalase gene used is 64% identical to SEQ ID NO:5, it is clearly within the scope of sequences "substantially identical" to SEQ ID NO:5 as defined on page 9 of the specification.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 42-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trakulnaleamsai et al. in view of Short (US Patent 5,939,250).

Trakulnaleamsai et al. is discussed above. Trakulnaleamsai et al. do not use the methods of mutagenesis specifically recited in Claims 44-53 to produce the mutant catalases. They further disclose that some of the catalase mutants had increased catalase and/or peroxidase enzymatic activity than the wild type protein.

Short teaches a number of known techniques for directed mutagenesis for the development of modified enzymes with particularly desired properties that are absent or less

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pronounced in the wild-type enzyme, such as stability to heat or organic solvents. Short specifically teaches "error-prone PCR", "shuffling", "oligonucleotide-directed mutagenesis", "assembly PCR", "sexual PCR mutagenesis", "in vivo mutagenesis", "cassette mutagenesis", "recursive ensemble mutagenesis", "exponential ensemble mutagenesis", and "site-specific mutagenesis".

One of ordinary skill in the art at the time of filing would have been motivated to modify the nucleic acid sequence encoding the catalase of Trakulnaleamsai et al. using each of the methods taught by Short, including "error-prone PCR", "shuffling", "oligonucleotide-directed mutagenesis", "assembly PCR", "sexual PCR mutagenesis", "in vivo mutagenesis", "cassette mutagenesis", "recursive ensemble mutagenesis", "exponential ensemble mutagenesis", and "site-specific mutagenesis" in order to modify the amino acid sequence of the catalase such that the enzyme has a increased catalase and/or peroxidase activity relative to the wild-type enzyme. One of ordinary skill in the art at the time of filing would have a reasonable expectation of success because of the high level of knowledge in the field of nucleic acid mutagenesis and the teachings of Trakulnaleamsai et al. who successfully generated a variant of the *Bacillus stearothermophilus* catalase encoding nucleic acid using similar

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mutagenesis methods. Thus Trakulnaleamsai et al. and Short make obvious claims 42-53 drawn methods of generating a variant comprising obtaining a nucleic acid comprising a sequence substantially identical to SEQ ID NO: 5 and modifying, deleting or adding one or more nucleotides in said sequence to another nucleotide, wherein the modifications are introduced by error-prone PCR (claims 42-44), shuffling (claims 42, 43 and 45), oligonucleotide-directed mutagenesis (claims 42, 43 and 46), assembly PCR (claims 42, 43 and 47), sexual PCR mutagenesis (claims 42, 43 and 48), in vivo mutagenesis (claims 42, 43 and 49), cassette mutagenesis (claims 42, 43 and 50), recursive ensemble mutagenesis (claims 42, 43 and 51), exponential ensemble mutagenesis (claims 42, 43 and 52), or site-specific mutagenesis (claims 42, 43 and 53).

Claims 42, 43, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trakulnaleamsai et al. in view of Short (US Patent 6,479,258).

Trakulnaleamsai et al. is discussed above. Trakulnaleamsai et al. do not use the methods of mutagenesis specifically recited in Claims 44-53 to produce the mutant catalases. They further disclose that some of the catalase mutants had increased catalase and/or peroxidase enzymatic activity than the wild type protein.

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Short teaches a number of known techniques for non-stochastic methods of directed mutagenesis for the development of modified enzymes with particularly desired properties that are absent or less pronounced in the wild-type enzyme, such as stability to heat or organic solvents. Short specifically teaches "gene reassembly", and "gene site saturated mutagenesis".

One of ordinary skill in the art at the time of filing would have been motivated to modify the nucleic acid sequence encoding the catalase of Trakulnaleamsai et al. using the methods taught by Short, including "gene reassembly", and "gene site saturated mutagenesis" in order to modify the amino acid sequence of the catalase such that the enzyme has a increased catalase and/or peroxidase activity relative to the wild-type enzyme. One of ordinary skill in the art at the time of filing would have a reasonable expectation of success because of the high level of knowledge in the field of nucleic acid mutagenesis and the teachings of Trakulnaleamsai et al. who successfully generated a variant of the *Bacillus stearothermophilus* catalase encoding nucleic acid using similar mutagenesis methods. Thus Trakulnaleamsai et al. and Short make obvious claims 42, 43, 54, and 55 drawn methods of generating a variant comprising obtaining a nucleic acid comprising a sequence substantially identical to

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SEQ ID NO: 5 and modifying, deleting or adding one or more nucleotides in said sequence to another nucleotide, wherein the modifications are introduced by gene reassembly (claims 42, 43 and 54), or gene site saturated mutagenesis (claims 42, 43 and 55).

The information disclosure statement filed 10-3-02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The reference cited from 09/922,185 have not been considered as no copies of these references have been provided and no IDS has been recieved by the Office in 09/922,185. It should be noted that it is not even clear if 09/922,185 is a related application to the instant application as it appears to be an incomplete application for which no information is available. If applicants wish this information to be considered copies of each reference are requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy,

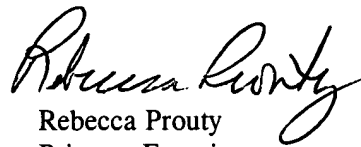
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can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Rebecca Prouty".

Rebecca Prouty
Primary Examiner
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